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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,931	03/12/2004	Christopher Gerard Quinn	22570-034001	6832

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EXAMINER	
NASSER, ROBERT L	

ART UNIT	PAPER NUMBER
3735	

NOTIFICATION DATE	DELIVERY MODE
09/23/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/799,931	QUINN ET AL.	
	Examiner	Art Unit	
	ROBERT L. NASSER	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7-21,24,26,29,32-38 and 40* is/are pending in the application.

4a) Of the above claim(s) *35 and 40* is/are withdrawn from consideration.

5)☒ Claim(s) *38* is/are allowed.

6)☒ Claim(s) *1-4, 7-18, 20, 21, 24, 26, 29, 32-34, 36, 37* is/are rejected.

7)☒ Claim(s) *19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Newly submitted claim 40 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The current claim is drawn to a method of producing a pressure sensing device, which is restrictable from the structure of the catheter, as the sensing device claimed could be made by a different method, including one that did not mention the low pass filter.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 40 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim 35 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/17/2007.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Pohndorf et al 5353800. Pohndorf shows a device with a pressure sensor 20, a pressure transmission catheter 16 with a proximal portion connected to the pressure sensor and a pressure transmission fluid in its lumen, a barrier, i.e. a flexible membrane (see column 4, line 26), where the barrier and fluid act as a low pass filter for

frequencies above 20 hz (see column 4, lines 46-56). The examiner notes that it is not exactly clear what "acts as a low pass filter for frequencies above X means, but that some of the frequencies above x are low pass filtered out.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 9, 13, 15, 21, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al 4846191 in view of Twardowski 6592565. Brockway shows a device with a pressure sensor 16, a pressure transmission catheter 20 having a proximal portion, a mid portion, and distal portion, a distal port, and a lumen extending thereto, where the proximal portion connects to the pressure sensor, a pressure transmission fluid in the lumen, a barrier 30 in the distal port to retain fluid in the lumen. It does not have a surface modification that promotes tissue in-growth. Twardowski is one of many implanted catheters which use a cuff on the surface of the catheter to promote ingrowth and help secure the catheter in place. Hence, it would have been obvious to modify Brockway to use such a cuff, so as to prevent movement of the catheter in use. The cuff is intended to be placed at the point where the catheter is inserted into the body. By analogy, the catheter of Brockway penetrates a blood vessel. It is the examiner's position that fair reading of the two references together would be to

place the cuff where the catheter penetrates the vessel, to stabilize the device. This would be the "distal portion" of the catheter. Claim 2 is rejected in that the device is connected to a telemetry unit (see column 5, lines 20-22). Claim 3 is rejected in that the exact method of forming the larger diameter has not been stated to be for a particular reasons or to solve a stated problem. As such, the method of forming the larger diameter would have been a mere matter of design choice for one skilled in the art. Claim 4 is rejected in that the distal end is counter-bored, or at least has equivalent structure to a counter bore, to create the larger diameter. The examiner notes that the method of forming the structure is a product by process limitation and will not serve to define over equivalent structure formed a different way. Claim 13 is rejected in that in figure 4, Brockway has a gel barrier that is recessed. Claim 15 is rejected in that the distal port is distal facing. Claim 36 is rejected in that distal portion of the catheter has a diameter that is larger than the middle portion. Claim 21 is rejected in that the exact shape of the lumen has not been stated to be for a particular reasons or to solve a stated problem. As such, the shape of the lumen would have been a mere matter of design choice for one skilled in the art.

Claims 1-4, 9, 13, 15, 21, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al 4846191 in view of Picha et al 5798055. Brockway shows a device with a pressure sensor 16, a pressure transmission catheter 20 having a proximal portion, a mid portion, and distal portion, a distal port, and a lumen extending thereto, where the proximal portion connects to the pressure sensor, a pressure transmission fluid in the lumen, a barrier 30 in the distal port to retain fluid in the lumen.

It does not have a surface modification that promotes tissue in-growth. Picha teaches a catheter (see figure 8) that measures a characteristic of blood, with a coating on the distal end of a substance to promote tissue ingrowth, to stabilize the device (see column 5, lines 53+). Hence, it would have been obvious to modify Brockway to use such a cuff, so as to prevent movement of the catheter in use. Claim 2 is rejected in that the device is connected to a telemetry unit (see column 5, lines 20-22). Claim 3 is rejected in that the exact method of forming the larger diameter has not been stated to be for a particular reasons or to solve a stated problem. As such, the method of forming the larger diameter would have been a mere matter of design choice for one skilled in the art. Claim 4 is rejected in that the distal end is counter-bored, or at least has equivalent structure to a counter bore, to create the larger diameter. The examiner notes that the method of forming the structure is a product by process limitation and will not serve to define over equivalent structure formed a different way. Claim 13 is rejected in that in figure 4, Brockway has a gel barrier that is recessed. Claim 15 is rejected in that the distal port is distal facing. Claim 36 is rejected in that distal portion of the catheter has a diameter that is larger than the middle portion. Claim 21 is rejected in that the exact shape of the lumen has not been stated to be for a particular reasons or to solve a stated problem. As such, the shape of the lumen would have been a mere matter of design choice for one skilled in the art.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al '191 in view of in view of Twardowski, as applied to claims 1-4, 9, 13, 15, 21and 36 above, further in view of Sisley 44053`13. Sisley further teaches that a cuff

like that of Twardowski will also prevent migration of bacteria. Hence, it would have been obvious to use the cuff to prevent infection or other harms from bacteria

Claims 8 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al '191 in view of in view of Twardowski, as applied to claims 1-4, 9, 13, 15, 21and 36 above, further in view of Bricault et al 5520664. Bricault further teaches that a cuff like that of Twardowski will also improve the seal of the catheter to the tissue (see column 10). Hence, it would have been obvious to use the cuff to help anchor the device in place.

Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al '191 in view of Twardowski, as applied to claims 1-4, 9, 13, 15, 21, and 36 above, further in view of Brockway et al 6296615. With respect to claim 5, Brockway et al '615 further teaches providing a surface modification, such as an antithrombotic coating, to increase the hemo-compatibility of the system (see column 6, lines 36-49). Hence, it would have been obvious to modify Brockway '191 to use such a coating, to increase the hemo-compatibility. Claim 10 is rejected in that the coating is a layer. Claims 11 and 12 are rejected in that Brockway '615 further teaches providing a removable tube over the end of the device to protect the end prior to use (see column 6, lines 50-58). As such, it would have been obvious to modify Brockway '191 to use such a cover, to provide protection for the tip. The tube is only connected at the distal end.

Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al '191 in view of Picha et al, as applied to claims 1-4, 9, 13, 15, 21, and 36 above, further in view of Brockway et al 6296615. With respect to claim 5, Brockway

et al '615 further teaches providing a surface modification, such as an antithrombotic coating, to increase the hemo-compatibility of the system (see column 6, lines 36-49). Hence, it would have been obvious to modify Brockway '191 to use such a coating, to increase the hemo-compatibility. Claim 10 is rejected in that the coating is a layer. Claims 11 and 12 are rejected in that Brockway '615 further teaches providing a removable tube over the end of the device to protect the end prior to use (see column 6, lines 50-58). As such, it would have been obvious to modify Brockway '191 to use such a cover, to provide protection for the tip. The tube is only connected at the distal end.

Claims 14 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al '191 in view of Twardowski, as applied to claims 1-4, 9, 13, 15, 21 and 36 above, further in view of Pohndorf et al 5353800. With respect to claim 14, Pohndorf teaches that a membrane is a known barrier to close a pressure transmitting carrier. Hence, it would have been obvious to modify Brockway '191 to use a membrane as the barrier, as it is merely the substitution of one known equivalent barrier for another. Claim 20 is rejected in that Pohndorf teaches that a helical catheter is a known PTC. As such, it would have been obvious to modify Brockway '191 to be a helical catheter, as it is merely the substitution of one known configuration for another.

Claims 14 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al '191 in view of Picha et al, as applied to claims 1-4, 9, 13, 15, 21 and 36 above, further in view of Pohndorf et al 5353800. With respect to claim 14, Pohndorf teaches that a membrane is a known barrier to close a pressure transmitting

carrier. Hence, it would have been obvious to modify Brockway '191 to use a membrane as the barrier, as it is merely the substitution of one known equivalent barrier for another. Claim 20 is rejected in that Pohndorf teaches that a helical catheter is a known PTC. As such, it would have been obvious to modify Brockway '191 to be a helical catheter, as it is merely the substitution of one known configuration for another.

Claims 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al '191 in view of Twardowski, as applied to claims 1-4, 9, 13, 15, 21 and 36 above, further in view of Itoigawa et al 5807265. Itoigawa shows an alternate PTC where the distal port is side facing. As such, it would have been obvious to modify Brockway '191 to use a side facing port, as it is merely the substitution of one known configuration for another.

Claims 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al '191 in view of Picha et al, as applied to claims 1-4, 9, 13, 15, 21 and 36 above, further in view of Itoigawa et al 5807265. Itoigawa shows an alternate PTC where the distal port is side facing. As such, it would have been obvious to modify Brockway '191 to use a side facing port, as it is merely the substitution of one known configuration for another.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al '191 in view of Twardowski, as applied to claims 1-4, 9, 13, 15, 21, and 36 above, further in view of Brockway et al 6409674. Brockway further teaches a stabilizer attached to a catheter to enhance the anchoring of the device and prevent

movement in use. As such, it would have been obvious to modify Brockway to provide a stabilizer, to improve the measurement process. With respect to claim 17, Brockway '674 teaches a dissolvable cap 640 on the device to aid in introducing the device. Hence, it would have been obvious to use such a cap, to prevent injury during insertion.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al '191 in view of Picha et al, as applied to claims 1-4, 9, 13, 15, 21, and 36 above, further in view of Brockway et al 6409674. Brockway further teaches a stabilizer attached to a catheter to enhance the anchoring of the device and prevent movement in use. As such, it would have been obvious to modify Brockway to provide a stabilizer, to improve the measurement process. With respect to claim 17, Brockway '674 teaches a dissolvable cap 640 on the device to aid in introducing the device. Hence, it would have been obvious to use such a cap, to prevent injury during insertion.

Claims 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al '191 in view of Twardowski, as applied to claims 1-4, 9, 13, 15, 21 and 36 above, further in view of Jackson 4160448. Jackson further teaches a PTC with a fill port, to maintain a proper level of fluid in the lumen. As such, it would have been obvious to modify Brockway '191 to use such a fill port, to increase the accuracy of measurement.

Claims 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al '191 in view of Picha et al, as applied to claims 1-4, 9, 13, 15, 21 and 36 above, further in view of Jackson 4160448. Jackson further teaches a PTC with a fill port, to maintain a proper level of fluid in the lumen. As such, it would have been

obvious to modify Brockway '191 to use such a fill port, to increase the accuracy of measurement.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson 4160448 in view of Brockway et al '191. Jackson shows a OTC with a catheter having an open proximal end connected to a pressure sensor 17, a fluid in the lumen, and a distal end closed by a sleeve 12 over the exterior of the catheter, which is an integral extension of the catheter. Brockway teaches that it is known to provide an internal pressure transducer and a transmitter to transmit the measurement results to the exterior of the body. Such an arrangement reduces the chances of infection and allows for improved patient mobility. Hence, it would have been obvious to modify Jackson to use an indwelling pressure transducer to improve patient comfort.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al '191 in view of Twardowski and Ruefer 5480711. Ruefer further teaches that eptfe is a known material used to promote ingrowth. Hence, it would have been obvious to modify the combination above to use eptfe for the cuff, as it is merely the simple substitution of one known equivalent material for another.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al '191 in view of Picha et al and Ruefer 5480711. Ruefer further teaches that eptfe is a known material used to promote ingrowth. Hence, it would have been obvious to modify the combination above to use eptfe for the cuff, as it is merely the simple substitution of one known equivalent material for another.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson 4160448 in view of Sisley. Sisley teaches placing a Dacron (polyester) cuff on a catheter like that of Jackson to prevent the migration of bacteria. Hence, it would have been obvious to modify Jackson to use such a cuff, to increase patient safety.

Claim 19 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 38 is allowable.

Claims 19 and 38 define over the art in that none of the art has the protrusions on the catheter.

Applicant's arguments filed 6/11/2008 have been fully considered but they are not persuasive.

With respect to claims 32-34, the examiner notes that the device of Pohndorf acts as a filter to some frequencies above 1, 5, or 10 hz.

Applicant's comments concerning the Twardowski reference were addressed above in the rejection.

With respect to claim 24, applicant contends that the examiner is "incorrect" in asserting that the balloon of Jackson is integral with the catheter. In response, the examiner asserts that applicant is, quite frankly, incorrect. There is no limiting definition of integral on the record. As such, the examiner is required to give the term its broadest reasonable interpretation. It is the examiner's position that two pieces that are connected to each other are integral with each other, i.e. a door knob is integral with a

door. In the current case, the balloon is connected to the catheter and extends therefrom. Hence, it meets the claim language.

Applicant has asserted that the cuff of Sisley is not located at a blood interface. It is the examiner's position that the limitation at issue is an intended use limitation. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Here, the cuff of the combination is capable of being located at the interface, as claimed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is 571 272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner
Art Unit 3735

RLN
September 12, 2008